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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,733	11/08/2006	Willem Theodoor Martinus Paier	313632001800	1678
25225 7590 02/03/2011 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040				
EXAMINER				
SAYALA, CHHAYA D				
ART UNIT		PAPER NUMBER		
1781				
NOTIFICATION DATE		DELIVERY MODE		
02/03/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficeSD@mofo.com

Office Action Summary

Application No.

10/575,733

Applicant(s)

PATER ET AL.

Examiner

C. SAYALA

Art Unit

1781

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-040)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-10, 12-15, 17, 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/45517.

The patent teaches a pet chew which is an edible thermoplastic that contains starch, which can be chemically altered, native or a mixture, in an amount 20 to 50 wt% (page 3, claim 1, claim 8), fiber (1 to 10 wt%), see page 3, lines 4-5, and water (8 to 12 wt% in the final form and 10 to 20 wt% in the initial mixture) (see page 3, line 4 and page 11, line 22). Note the use of vitamins and minerals, (page 4, lines 28-34), and up to 20 wt% plasticizers (page 10, lines 18-22) and preferably between 12 to 18 wt%. Of the plasticizers used, glycerol and polyols are disclosed at pages 4 & 10. Oils such as flax oil are shown at page 5, that inherently contain fatty acids. Lecithin is disclosed in the examples. Additives providing aroma is disclosed at page 10, lines 24-25. The starch is disclosed at reference claims 6-8, fiber at claim 9, plasticizer at claims 15-18. The water content of the thermoplastic mixture is shown at claim 1 as 10 to 20 wt%. Extrusion temperatures are disclosed at page 11, last full

paragraph. The pet chew can be formed by injection molding and the shapes are also given at page 12. Instant claims 2-4 are disclosed at page 4, lines 19-30. Instant claim 9 is disclosed at page 3, lines 30-32. Instant claim 13 is disclosed at page 11, lines 1-2. Claim 19 is written in a product-by-process format and depends from claim 1 and since claim 1 is clearly anticipated, then claim 19 is anticipated as well. With regard to claim 21, patentees claim this at claim 20.

2. Claims 1-4, 6-12, 14-15, 17, 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0552897.

The edible chew product of the patent consists of fiber (cellulose), 20-50 wt%, starch, wherein the patentee states that the starch includes amylaceous hydroxylates and mixtures derived from tubers, corn and wheat, (page 3, lines 38-50), about 30 to about 60 wt%, glycerol or sorbitol (1 to 15 wt%). See page 3, page 4, lines 44+. The fiber particles are about 5 to about 1000 microns (instant claim 11). Note flavoring substances at page 4, lines 44-48. Extruder temperatures are disclosed at page 5, lines 44-45. The moisture content is 12 to 35 wt% (see page 6, line 3, claim 7) in the final product and 20-50 wt% in the initial mixture (page 5, line 7). Note that the Example shows a moisture content of 10.82% in the initial mixture. Page 7, lines 1-7 shows that the extrudate was in the form ribbons and cut into pieces of about 3 inches, giving it a bar or a natural shape.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 11, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/45517 taken with EP 552897 and in view of EP 0838153.

The WO patent does not disclose the cellulose fiber length, and the mesh pore size and the injection molding temperatures as claimed herein at claim 18. However, the WO patent discloses that the product uses cellulose fibers, uses injection molding in forming the product (see page 3, lines 30-32; page 11, line 4). The EP '897 patent also drawn to a similar chew that contains the same ingredients, teaches the length of fibers as being between about 5 to about 1000 microns. One of ordinary skill in the art would have found it useful to incorporate such lengths in the invention of the WO patent, because of the similarity of the use of fiber ingredient (cellulose). With regard to the injection molding process in the WO patent, details of performing such a molding process is detailed in the EP '153 patent which describes making a beaded

extrudate from starch that has a size 3 to 10 mm. See col. 5, lines 50-59. The beads (or granulates) are then molded at barrel temperatures of 121 to 204°C. To incorporate such process details in the WO patent which indicates the making of the product therein by injection molding but fails to give any particulars would have been useful and obvious to the practitioner.

4. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/45517 in view of Leo (US Patent 5419283).

The WO patent does not disclose the use of maltose. However, Leo teaches the use of maltose, also for a dog chew, also for a starch containing chew, wherein the starch is modified starch as instantly claimed. To include maltose for its benefits as shown at col. 1, lines 49-54 would have been prima facie obvious.

Response to Arguments

Applicant's arguments filed 11/24/2010 have been fully considered but they are not persuasive.

Applicant has traversed the WO '517 patent applied by stating that the disclosure is drawn to a "thermoplastic protein" chew not a "thermoplastic starch" chew. The patent has been carefully reviewed and such a disclosure could not be found. It is submitted that the patent only discloses a thermoplastic chew. In fact, the disclosure describes a chew that includes an

embodiment that has an amount of protein and starch that is 50 wt% each (abstract, claim 1). Therefore, the reference could not be interpreted as being drawn to a 'thermoplastic protein' as applicant has characterized the reference, and the reference could not be withdrawn so that the claims can be allowed based on applicant's traversal.

Applicant states that the EP '897 should be withdrawn because the patent is not drawn to the type of starch claimed. However, the patent includes starch hydroxylates and therefore teaches the same starch as claimed.

Applicant has also submitted "Exhibit A" which is a copy of photographs, Figure 1 and Figure 2, in an attempt to overcome the rejection under 35 USC 103. Applicant states that the Figures show striking differences between samples #2 and #4 of Example 1 (this is in error, see Table 1). He states that the length after storage of sample #2 and sample #4 in the figures show that the modified starch sample provided better results with regard to the E-modulus and tensile strength and that the samples show a difference in length and surface details. He states that sample #2 has lower dimensional stability and its surface details are obscure. While the figures themselves are of poor quality and do not provide any objective evidence since there is nothing scientific about comparing photographs, the examiner failed to notice any surface details being better for sample #4 and the length itself being slightly more but not significant based on an undefined time lapse. However, the details pointed to at Table I have been reviewed and it is being held that the results therein are not

unexpected with regard to dimensional stability and other related physical properties, for the following reasons:

When considering the evidence submitted to show unexpected results, it becomes necessary to weigh such evidence in terms of the state of the art and the level of skill in the art. "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967). If the prior art teachings lead to a general expectation of a property that applicant now holds to be unexpected, it cannot be said that the claimed invention is unobvious. Where the unexpected properties of a claimed invention are not shown to have a significance equal to or greater than the expected properties, the evidence of unexpected properties may not be sufficient to rebut the evidence of obviousness. *In re Nolan*, 553 F.2d 1261, 1267, 193 USPQ 641, 645 (CCPA 1977) (Claims were directed to a display/memory device which was *prima facie* obvious over the prior art. The court found that a higher memory margin and lower operating voltage would have been expected properties of the claimed device, and that a higher memory margin appears to be the most significant improvement for a memory device. Although applicant presented evidence of unexpected properties with regard to lower peak discharge current and higher luminous efficiency, these properties were not shown to have a significance equal to or greater than that of the expected higher memory margin and lower operating voltage. The court held

the evidence of nonobviousness was not sufficient to rebut the evidence of obviousness.); *In re Eli Lilly*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (Evidence of improved feed efficiency in steers was not sufficient to rebut *prima facie* case of obviousness based on prior art which specifically taught the use of compound X537A to enhance weight gain in animals because the evidence did not show that a significant aspect of the claimed invention would have been unexpected.).

The evidentiary references below relate to the state of the art in this field.

** The prior art discussion of Merrill (US Patent 5459258) relating to biodegradable molded articles using starch, states at col. 1, line 45+, as follows:

Starch has been evaluated for use as a polymer for use in manufacturing articles. It is very susceptible to enzymatic digestion by the enzyme .alpha.-amylase which attacks the .alpha.-D (1-4) glucosidic linkages. These linkages can be cleaved in either physiological or environmental conditions. However, starches form weak and brittle products. Starch is not thermoplastic by itself and therefore cannot be melt processed into useful products by extrusion, compression molding, injection molding, calendaring, or fiber spinning without the addition of significant quantities of plasticizers.

Probably the greatest disadvantage of using starch as a manufacturing material is that due to its hydrophilic nature, the water content of an object made from starch is difficult to control. This can lead to undesirable changes in the physical properties of the object, since physical properties are strongly tied to water content.

At col. 2, lines 58+ :

In one embodiment, hydrophobicity of the continuous starch phase is achieved by the partial or complete esterification of starch. Preferred esterifying agents are of the formula RCO.sub.2 H , wherein R is a straight or branched C.sub.1 - C.sub.6 alkyl group, or mixtures thereof, or activated derivatives of the acids or mixtures of acids. The degree of hydrophobicity and physical properties of the

modified starch, including processability, can be manipulated by the selection of the esterifying agent or agents.

** Buehler et al. (US Patent 5316578) is drawn to producing a chemically modified starch to be used for making thermoplastically processible starch melt that is then used to make shaped products (col. 1, lines 5-15). In providing chemically modified starch for purposes of making shaped products, col. 5, lines 35-50 states:

The process of the present invention has numerous advantages. It permits operation without the necessity of incorporating any external or added water. It has been found that there is less shrinkage of the products produced from the melt of the present invention; thus, the shapes made from the melt are more stable than those of the prior art. This is believed to be due to the high rate of solidification of the inventive melts.

The products have good mechanical properties (such as flexibility), as there is little or no embrittlement. Granules produced in accordance with the present invention have excellent shelf life due to their low water uptake. Moreover, their high stability at low melt viscosities means that such low viscosity melts retain the toughness needed to produce sheet materials.

** Lay et al. (US Patent 5095054) disclose that since starch is hydrophilic, to provide dimensional stability, increase elasticity, etc, it would be beneficial to introduce hydrophobicity by means of hydrophobic thermoplastic materials. See col. 2 and col. 3. The patentee notes that providing such hydrophobicity to starch improves dimensional stability, provides markedly less shrinkage.

** Lim et al. (US Patent 5320669) discloses crosslinking cereal grain starch for purposes of preparing molded articles such as package articles, pet food, etc. See col. 9. The crosslinking of starch provides products that can be

molded and have a higher resistance to disintegration and "will remain substantially intact for a more extended period of time than articles made without crosslinking" (i.e. native starch).

Therefore, when considered together with prior art knowledge and state of the art, taken with the level of skill in the art, the evidence presented at Table 1 and discussed above, *does not* establish unexpected results; one of ordinary skill in the art would have expected less shrinkage and greater dimensional stability simply by using modified starches (as shown by prior art), which would introduce hydrophobicity to hydrophilic starch. Note that the Lim et al. disclosure establishes that the prior art evidence presented here is analogous art and one of ordinary skill would have been aware of the developments in this art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the

advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Sayala whose telephone number is (571) 272-1405. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/C. SAYALA/
Primary Examiner, Art Unit 1781**